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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/494,751	01/31/2000	Bernard Rees Smith	0769.00136	3862

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EXAMINER

DO, PENSEE T

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 11/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/494,751

Applicant(s)

SMITH ET AL.

Examiner

Pensee T. Do

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 September 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 63-90 is/are pending in the application.
- 4a) Of the above claim(s) 63-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 77-90 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 63-90 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Amendment Entry & Claim Status***

The amendment filed on September 3, 2002 and the Information Disclosure Statement filed on November 4, 2002 have been acknowledged and entered.

Claims 1-62 have been canceled. Claims 63-76 are non-elected. Claims 77-90 are examined.

### ***Withdrawn Rejection(s)***

Rejections under 35 USC 112, 2<sup>nd</sup> paragraph, 102 and 103 are withdrawn herein.

## **NEW GROUNDS OF REJECTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 77-90 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4)

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the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

*The nature of the invention:* - the instant invention is directed to a kit for detecting autoantibodies to thyroid stimulating hormone receptor (TSHR) or at least a TSHR fragment which kit comprises a source of TSHR or a TSHR fragment, said TSHR or TSHR fragment each having at least a first and second distinct epitope regions, wherein autoantibodies to said TSHR or TSHR fragment bind to the first epitope region but not said second epitope region; at least one antibody or fragment thereof, that binds to said second epitope region of the TSHR or TSHR fragment.

*The state of the art:* - the prior art fails to teach a kit comprising a TSHR or a TSHR fragment comprising two distinct epitope regions.

*The predictability or lack thereof in the art:* - in view of the lack of teachings in the prior art that show or suggests TSHR or TSHR fragment with two distinct epitopes regions for binding to autoantibodies and antibody respectively, the level of predictability is low. The specification fails to teach specific epitope regions on the TSHR or TSHR fragment. Without the specific epitope regions, antibodies (which binds to the second epitope region) cannot be generated.

*The amount of direction or guidance present:* - the instant specification fails to provide guidance on how to generate antibodies that binds to the specific epitope region on the TSHR or TSHR fragment.

The presence or absence of working examples:- there is no examples in the specification that show generation of antibody which specifically binds to the second epitope region or specific epitope region to which autoantibodies would bind.

The quantity of experimentation necessary: - it would require an undue amount of experimentation for a skilled artisan to make and use the invention as claimed.

The relative skill of those in the art: The level of skill in the art is high.

The breadth of the claims:- the claimed kit is directed to a TSHR or TSHR fragment comprising two distinct epitope regions wherein autoantibodies bind to the first epitope region and at least one antibody or fragment thereof binds to the second epitope region.

The instant specification fails to describe specific epitope regions on the TSHR or TSHR fragment. Any four amino acid would constitute an epitope. However, in order to generate antibodies that binds to a specific region on the TSHR or fragment, such specific region has to be known. An undue amount of experimentation would be required to identify any and all the possible epitopes found on the TSHR or fragment to enable the claimed kit.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 703-308-4398. The examiner can normally be reached on Monday-Friday, 7:00-3:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-746-5291 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Pensee T. Do  
Patent Examiner  
November 14, 2002



CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP ~~1800~~ 1641